SEP 2 2 2003

510(k) SUMMARY

510(k) NUMBER:	K031889
SUBMITTED BY:	Applied Medical Resources Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA-92688 (949) 713-8000
CONTACT PERSON:	Mary Jo Stegwell Vice President of Regulatory Affairs and Clinical Programs
DATE OF PREPARATION:	September 12, 2003
NAME OF DEVICE:	Wound Retractor
CLASSIFICATION NAME:	Drape, Surgical, General & Plastic Surgery. (Regulation Number 21CFR 878.4370, Surgical drape and drape accessories).
TRADE NAME:	Alexis™ Wound Retractors
PREDICATE DEVICE:	Dexterity Protractor (Protector Retractor and Protector Retractor with drape, K954824), Medical Creative Technologies, Inc. Colmar, PA.
DESCRIPTION	The Applied Wound Retractor consists of a flexible polymer membrane formed into the shape of a cylinder. Attached to each open end of the cylinder are two semi-rigid polymer rings.

SUMMARY STATEMENT: The Applied Alexis Wound Retractor is indicated for use in retracting and protecting an abdominal incision during laparoscopic or open surgery. It is intended to allow the surgeon to access the abdominal cavity through an atraumatically retracted wound that provides maximum exposure with minimum incision size. Further, once positioned in the abdominal wall, the Alexis Wound Retractor is intended to protect against wound contamination. To perform these functions, Alexis Wound Retractors are constructed as a cylindrical membrane sheath that has two rings attached to each open end. The rings are molded in a plastic material. The Wound Retractor package also includes an incision template.

The device will be manufactured in four sizes, small, medium, medium-large and large. The small and medium products will have two additional indications. These models have an iris valve feature that allows the wound protector to be adjusted from fully open to fully closed. This capability allows Alexis to seal the incision area or to seal around a trocar. The procedure may

then be returned to fully laparoscopic and an additional trocar may be placed through the incision site.

The Wound Retractor is simple to set up and easy to use. A sterile skin marker is used to mark an incision line at the surgery site and the incision is made. The Wound Protecting sheath is placed in position through the incision with one ring inside the abdomen. The external ring is placed in traction and folded over itself until it contacts the abdomen. Once securely in place, the Alexis Wound Retractor keeps the incision open during the procedure. The wound protective sheath lines the incision and protects it from contamination and injury from instruments during the procedure.

The Alexis Wound Retractor has been found non-toxic and non-irritant when tested in accordance with ISO 10993, Part I: Biological Evaluation of Medical Devices. The materials used in the manufacturing of the Alexis Wound Retractor have been tested in accordance with applicable standards and was determined to pass tensile strength, elongation, (ASTM D 412) and Tear Strength (ASTM D 624). Functional performance testing has been completed and has passed the required testing.

The Applied Wound Retractor is a disposable, single-use device and is packaged inside a Tyvek/Mylar peel pouch, which is standard packaging material for Applied's products. The packaged product is then placed in an outer product shelf pack.

The Applied Wound Retractor is sterilized using 100% EO. Applied's 100% EO sterilization cycle provides a sterility assurance level of 10^{-6}. Sterilization validation for Applied Medical's EO cycle uses three half-cycle validation runs, which incorporate biological indicators and temperature monitors distributed throughout the load to verify gas penetration and profile temperature distribution. Spore strip biological indicators of *B. subtillis* var. *niger* with a population of 10^{6} are used to monitor routine finished product sterilization loads. Sterilant residue levels will be in compliance with ANSI/AAMI/ISO 10993-7:1995 for limited exposure devices which is 20 mg ethylene oxide and 12 mg ethylene chlorohydrin.

The Alexis Wound Retractor is substantially equivalent to predicate devices in design methodology, principle of operation and clinical utility. The device introduces no new safety or effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2003

Ms. Mary J. Stegwell
Vice President of Regulatory Affairs and Clinical Programs
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K031889
Trade/Device Name: Alexis™ Wound Retractors
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: June 13, 2003
Received: July 1, 2003

Dear Ms. Stegwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Alexis Wound Retractor's "Indications for Use" as required.

510(k) Number: K031889

Device Name: Alexis Wound Retractor

Indications for Use: The Applied Alexis Wound Retractor is indicated for use to:

- Access the abdominal cavity during surgery through an atraumatically retracted incision.
- Deliver maximum exposure of the abdominal cavity with minimum incision size.
- Protect against wound contamination during laparoscopic and open surgery.

The smaller two sizes of Alexis are also intended to be used to:

- Seal off the incision opening to permit insufflating the peritoneum.
- Convert the incision wound to an additional trocar port site.

Susan Runmeasure

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K031889

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)